



74 DEC 13 1993 IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of) Examiner: M. Woodward
ROGER P. EKINS)
Serial No. 07/984,264) Group Art Unit: 1813
Filed: December 1, 1992,) Supplement to Response to
For: DETERMINATION OF AMBIENT) Paper No. 12
CONCENTRATION OF SEVERAL)
ANALYTES) *REDENIED*
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December 10, 1993
Date of Certificate

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SUPPLEMENTAL RESPONSE TO FIRST OFFICIAL ACTION

Applicant in the above-identified patent application submits herewith the Declaration of Professor Ivan Maurice Roitt by way of supplement to the Amendment and Request for Reconsideration Under 37 C.F.R. §1.111, filed November 23, 1993, in response to the August 23, 1993 Official Action. The Examiner is respectfully requested to consider and make the enclosed Declaration of record in the present application.

The Declaration submitted herewith provides clear evidence to support applicant's position that the prior art rejection based on applicant's published international patent application WO 84/01031 (Ekins '031) and U.S. Patent 4,591,570 (Chang) cannot be maintained.

The §103 rejection based on the combined disclosures of Ekins '031 and Chang is premised on the Examiner's interpretation of Chang to the effect that Chang operates under the ambient analyte conditions described in Ekins '031.

The Declaration of Professor Roitt establishes, however, that Chang does not teach or suggest Professor Ekins' ambient analyte methodology to the person of ordinary skill in the art, and provides a scientific basis for his conclusion in this regard. See paragraph 5 of the Declaration of Professor Ivan Maurice Roitt. Since the Examiner's argument with respect to the asserted obviousness of the invention claimed in claims 12-28 rests on a false premise, the argument is plainly invalid.

Professor Roitt's Declaration further states that Ekins' '031, itself, does not teach the skilled person the advantages of using less 0.1 V/K moles of binding agent in the assay described therein. As noted by Professor Roitt, the amounts of binding agent exemplified in Ekins '031 are all in considerable excess of 0.1 V/K moles, as required in the practice of the present invention.

With regard to the advantages offered by the present invention, as compared to Ekins '031 and Chang, Professor Roitt states:

The above application [U.S. Serial No. 07/984,264] has the considerable practical advantage over '031 as the use of less than 0.1 V/K moles of binding agent means that a small amount of analyte is removed from the total, irrespective of the analyte concentration.

I believe that because people skilled in the art would intuitively be convinced that extremely small amounts of binding agent would be swamped by analyte, they would not normally even bother to apply the Laws of Mass Action to calculate the fractional occupancy as the above application has done; frankly, I was astonished that these microspots provided a workable system with the advantages set out above and am quite convinced that the disclosure of Ekins '031 would not have led the person of ordinary skill in the art to reduce further the amount of binding agent used in the assay of Ekins '031, especially in light of the prevailing view in the field, and

certainly not to the realization of the advantages set out above. [Emphasis in original.]

From the statements contained in Professor Roitt's Declaration, it is clear that the methods, devices and kits for determination of ambient concentration of a plurality of analytes, as disclosed and claimed in the present application, could not have been arrived at by one of ordinary skill in the art from the disclosures of Ekins '031 or Chang, considered singly or together.

For the reasons set forth in applicant's initial response to the August 23, 1993 Official Action, and further in view of the Declaration of Professor Ivan Maurice Roitt submitted herewith, it is again respectfully requested that the objections and rejections set forth in the August 23, 1993 Official Action be withdrawn and that this application be passed to issue, and such action is earnestly solicited.

Respectfully submitted,

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Enclosure: - Declaration of Professor Ivan Maurice Roitt